

Application No. 10/025,472

Amdt. dated January 7, 2004

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Docket No. 1501-1148

REMARKS/ARGUMENTS

Claims 11-28 and 35 are pending in the application.

Claims 11, 13 and 15-25 are amended and are believed to address the 35 USC §101 rejections noted in the Official Action.

Regarding the rejection of claim 23 under 35 USC §112, second paragraph, the *American Heritage Dictionary of the English Language*, Fourth Edition by Houghton Mifflin Company defines mesh as "an openwork fabric or structure; a net".

Applicant asserts that one of ordinary skill in the art would be able to determine that "made of mesh" as noted in the Official Action and "net-shaped" are essentially the same and as such are sufficiently self-descriptive to define claim 23 with sufficient specificity. 10

Claims 11-14, 18-20, 26-28 and 35 are rejected as anticipated by DEEM et al. (WO 00/609995).

Reconsideration and withdrawal of the rejection are respectfully requested because the reference does not disclose or suggest at least one stabilizing element at each leaflet base so that the leaflet bases are

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interconnected by the stabilizing element which is extended across an atrial side of the cardiac valve as recited in claim 11 of the present application.

By way of example, page 6, lines 19-21 of the present application disclose that stabilizing element or elements 14 is arranged between the two leaflet bases 8 and 10 respectively, at the atrial side of the prolaps, so that the leaflet bases 8, 10 are interconnected by the stabilizing elements 14. As seen in Figure 8 of the present application, the atrial side is the right side of orifice O and the ventricle chamber is on the left of the plane O such that the direction of blood stream is from the right to left. As further seen in Figure 8, the stabilizing element 14 extends across the atrial side of the cardiac valve such that respective ends 22 and 24 of the stabilizing member 14 connect leaflet bases 8 and 10.

The device of DEEM et al., specifically the device shown in Figures 69A-72B (noted in the Official Action as providing support for a stabilizing element) show the conventional technique of connecting the valve at the edges of the valve. Specifically, page 43, line 24 through page 53, line 3 of DEEM et al. disclose various devices for

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connecting valve leaflets together. Each of the devices connect the free ends of the valve as seen in the figures and as stated on page 43, line 34 through page 44, line 1 and page 50, lines 23-24. Such edge-to-edge repair and its disadvantages are discussed on page 2, line 25 - page 3, line 8 with respect to the background of the invention of the present application.

DEEM at al. do not disclose or suggest more than that disclosed in the above-noted passage and only teach edge-to-edge repair. Accordingly, DEEM et al. do not disclose base-to-base repair such that at least one stabilizing element is at each leaflet base so that the leaflet bases are interconnected and so that the stabilizing element extends across the atrial side of the cardiac valve as recited in claim 11 of the present application.

As the reference does not disclose that which is recited, the anticipation rejection is not viable. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 12, 13 and 14 also recite at least one stabilizing element at an atrial side of a valve annulus

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and that the leaflet bases are interconnected by means of the stabilizing element which is arranged to extend across the atrial side of the cardiac valve. The comments above regarding claim 11 are equally applicable to claims 12, 13, and 14.

Claims 18-20 and 26-28 depend from one of claims 11-14 and further define the invention and are also believed patentable over the cited prior art.

Claim 35 recites a means for interconnecting and reducing a distance between anterior and posterior leaflet bases of a cardiac valve. As previously stated, claim 35 is written in 35 USC §112 sixth paragraph means-plus-function format. Accordingly, any applied prior art must teach identical or equivalent structure that performs the exact recited function of interconnecting and reducing the distance between the anterior and posterior leaflet bases of the cardiac valve as disclosed on page 5, line 13 through page 6, line 26 of the present application. Such an analysis is absent in the Official Action.

Applicants believe that an edge-to-edge repair as disclosed in DEEM et al. is not identical or equivalent structure that performs the exact recited function of

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interconnecting and reducing a distance between the anterior and posterior leaflet bases on an atrial side of the cardiac valve as recited in claim 35 of the present application. Accordingly, a complete 35 USC 112, sixth paragraph analysis that indicates identical or equivalent structure that performs the exact recited function of interconnecting and reducing the distance between the anterior and posterior leaflet bases of the cardiac valve as disclosed on page 5, line 13 through page 6, line 26 of the present application or withdrawal of the rejection is respectfully requested.

Claims 11, 15-17 and 21-22 are rejected as anticipated by NORTHROP III 5,593,424. This rejection is respectfully traversed.

The Official Action has indicated that Figure 10 of NORTHROP III discloses a stabilizing element interconnecting the leaflet bases. However, Figure 10 of NORTHROP III also teaches edge-to-edge valve repair.

In addition, NORTHROP III teaches another conventional valve repair technique. Specifically, as seen in Figure 7 of NORTHROP III, the conventional technique of reducing the circumference of the valve is shown. As

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disclosed on column 5, lines 22-45 of NORTHROP III, by having suture entry and exit holes a distance D' further apart than the distance D between suture holes 24, 26, a circumference of the vascular structure is reduced. Neither of the techniques disclosed by NORTHROP III is base-to-base repair such that at least one stabilizing element is at each leaflet base so that the leaflet bases are interconnected and so that the stabilizing element extends across the atrial side of the cardiac valve as recited in claim 11 of the present application.

As the reference does not disclose that which is recited, the anticipation rejection is not viable. Reconsideration and withdrawal of the rejection are respectfully requested.

By way of further explanation, the edge-to-edge technique as taught by both DEEM et al. and NORTHROP III and the reducing the valve circumference technique as taught by NORTHROP III influence the geometry of the vascular structure by either shaping the valve into a double orifice to reduce the cross-sectional area or by reducing the cross-sectional area available for blood circulation.

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In contrast, the technique of the present invention as recited in claims 11-28 and 35 does not influence the available cross-sectional area surrounded by the annulus. This is achieved by bringing the valve bases toward one another, which brings the valve back to its normal position.

Applicant notes that claim 24 of the present application, which recites that an intermediate section of the strip or band is shaped in the form of a ring and claim 25, which recites that an intermediate section of the strip or band is shaped in the form of a circular disc were not rejected on the merits. Since the formal matters are believed addressed, claims 24 and 25 are believed patentable regardless of the patentability of the claims from which they depend.

In view of the present amendment and the foregoing remarks, it is believed that the present application should be in condition for allowance. Reconsideration and allowance are respectfully requested.

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